

**SERIAL NO. 10/643,006**

**PATENT APPLICATION**

**IN THE UNITED STATES PATENT & TRADEMARK OFFICE**

Appellant:	LOVETT et al.	Examiner:	Nguyen, H.
Serial No.:	10/643,006	Group Art Unit:	3736
Filed:	August 18, 2003	Docket No.:	GUID.060PA
Confirmation No.:	2975	Customer No.:	51294
Title:	SLEEP STATE CLASSIFICATION		

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this paper is being electronically transmitted by EFS-WEB to the United States Patent and Trademark Office on August 31, 2011.

By: Tracey M. Dotter/  
Tracey M. Dotter

**APPELLANT'S STATEMENT IN SUPPORT OF  
PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This statement is presented by Appellant in compliance with the USPTO *Official Gazette* Notice of July 12, 2005 entitled "New Pre-Appeal Brief Conference Pilot Program". Appellant is requesting a pre-appeal brief conference on the belief that the rejections of record are clearly not proper and are without merit. Appellant's request is based upon a clear legal or factual deficiency in the rejections. As such, Appellant believes this request for pre-appeal review is appropriate.

In the Final Office Action of June 15, 2011, claims **86, 88, 89, 91-93, 95-99, 101, 104, 106, 107, 109, 112-117, and 121** were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,902,250 (Verrier et al.), hereinafter "Verrier", in view of U.S. Patent Application Publication US 2005/0119711 (Cho et al.), hereinafter "Cho", and further in view of U.S. Patent 5,187,657 (Forbes). Other dependent claims were rejected under 35 U.S.C. §103(a) as being unpatentable over Verrier in view of Cho and Forbes, and further in view of other secondary references.

Independent method claim **86** recites *inter alia* "sensing pectoral muscle tone using a sensor disposed on a cardiac rhythm management device implanted in a pectoral

region” and “detecting REM sleep status based on the pectoral muscle tone”.

Independent device claim **104** similarly recites a “first sensor disposed on the implantable cardiac rhythm management device, the first sensor configured to sense muscle tone in the pectoral region of the patient and to detect REM sleep status based on the pectoral muscle tone”.

In rejecting these independent claims, the Examiner cites Verrier as disclosing *inter alia* sensors for detecting sleep-wake status and for detecting REM sleep, and a classification system for classifying sleep state. The Examiner cites Cho as disclosing *inter alia* an implantable cardiac rhythm management device that is implanted into the chest of the patient, with a “sensor 62 disposed on at least a portion of the ... device”. The Examiner then contends that it would have been obvious to make the invention of Verrier perform the sleep state classification using an implantable cardiac rhythm management device “with a sensor disposed on it as taught by Cho ... wherein when the device is implanted, the sensor would therefore by [sic] in communication with the pectoral muscles due to the location of implantation.”

On page 4 of the Final Office Action, the Examiner acknowledges that neither Verrier nor Cho discloses the condition associated with REM-sleep comprises sensing a muscle tone in a pectoral region of the patient using the first sensor. The Examiner however contends that Forbes teaches that it is “well known” within the art to use a muscle atonia sensor to detect REM sleep, citing column 3, lines 13-16, and further contends that:

“... it would have been obvious to substitute the REM sensed condition of Verrier et al as modified by Cho et al with that of sensing a muscle tone in a pectoral region of the patient as taught by Forbes as an equally as effective means to detect REM sleep in the now implanted device, wherein due to the modification of Verrier et al to be implantable by Cho et al the device with its sensor is implanted in the chest and therefore by the pectoral muscles allowing sensing of the pectoral muscle tone to effectively determine REM sleep status as taught by Forbes.” (pp. 4-5 of the Office Action)

In response, we begin by reiterating one of the arguments made in our response of April 15, 2011. Of the three asserted references, Verrier and Forbes are the ones that specifically discuss REM sleep to any significant extent. (REM sleep is mentioned only

once in Cho, and only in the background section.) Verrier discusses detecting REM sleep using a sensor 12 that is applied to the patient's eyelid – see FIG. 1 and column 6, line 23 to column 7, line 16. Forbes discusses detecting REM sleep using sensors 114 that are attached to an exterior surface of the patient – see FIG. 1; column 4, lines 42-68; and column 1, lines 35-52. Thus, even though Forbes contains the vague statement at column 3, lines 13-15 that “[f]or example, eye movement sensors, muscle atonia sensors, or brain wave sensors can be used for REM sleep state detection”, the reader would interpret this statement in the context of the Forbes disclosure, which is directed to a system that utilizes sensors or electrodes that are applied to the body surface, i.e., skin, of the patient.

Thus, none of the references fairly teaches (a) detecting REM sleep status using “a sensor disposed on a cardiac rhythm management device [that is] implanted in a pectoral region” as recited in claim 86, or even (b) detecting REM sleep status using any sensor implanted in a pectoral region of the patient, or even (c) detecting REM sleep status using any implanted sensor. In view of at least this missing element, the claimed invention would not have been obvious, even if the skilled person would have been provided with the asserted combination of references.

The Final Office Action dismisses the above argument as “taking a piece meal approach to the references”, stating further that one cannot show nonobviousness by “attacking references individually” where the rejections are based on combinations of references. Appellant respectfully points out that contrary to the Examiner's characterization, the above argument is the opposite of a “piecemeal” approach. In a piecemeal approach, an applicant may argue, in connection with an obviousness rejection based on a combination of three references X, Y, and Z, that claim feature A is missing from reference X, claim feature B is missing from reference Y, and claim feature C is missing from reference Z, ignoring the possibility that claim feature A may be present in references Y or Z, that claim feature B may be present in references X or Z, and that claim feature C may be present in references X or Y. Appellant's argument is the opposite of this, i.e., it is global rather than piecemeal. It points out a claim feature that is missing from *all* of the asserted references, not just one of the references. Contrary to the Examiner's assertion, Appellant's argument does not “attack the references individually” but attacks them, i.e., points out their shortcomings, collectively as a group.

Therefore, since none of the references Verrier, Cho, or Forbes teaches detecting REM sleep status using an implanted sensor, the combination of those references cannot logically teach that claim feature either. The rejection of independent claims 86, 104, and their respective dependent claims under § 103 based on the combination of Verrier, Cho, and Forbes cannot be sustained.

We further point out that in the course of rejecting claims 86 and 104, the Examiner inadvertently mischaracterizes the scope and content of at least the Cho and Forbes references.

With regard to Cho: both paragraphs 7 and 8 of the Final Office Action state that Cho discloses a sensor “disposed on” the implanted cardiac rhythm management device. In paragraph 8, the Examiner uses this alleged disclosure to draw the conclusion that “the sensor would therefore [be] in communication with the pectoral muscles due to the location of implantation” when the device is implanted. The undersigned has reviewed paragraphs 0016, 0032-0033, and 0043-0044 of Cho, which are cited in the Office Action as providing the disclosure of a sensor “disposed on” the implanted device. The sensor at issue is described by Cho as an activity sensor, and is shown in Cho’s FIG. 1 as sensor 62. However, the undersigned can find no teaching or hint in the cited paragraphs that the sensor is “disposed on” the implanted device. Appellant submits that the contention that Cho’s sensor is disclosed as being “disposed on” the implanted cardiac rhythm management device is erroneous, and the conclusion drawn from that erroneous contention (“the sensor would therefore [be] in communication with the pectoral muscles due to the location of implantation”) is consequently also erroneous. Since the rejection is premised on an erroneous assessment of the scope and content of Cho, the rejection of claims 86 and 104, and of their respective dependent claims, cannot be sustained.

With regard to Forbes: in paragraph 9 of the Final Office Action, the Examiner concludes the rejection of independent claims 86 and 104 with the statement that it would have been obvious ... to substitute the REM sensed condition of Verrier as modified by Cho with that of “sensing a muscle tone in a pectoral region of the patient as taught by Forbes as an equally as effective means to detect REM sleep” in the now implanted device. Appellant submits that the quoted portion of this statement inadvertently mischaracterizes Forbes in two ways: (1) it assumes Forbes teaches sensing a muscle

tone “in a pectoral region” of the patient; and (2) it assumes Forbes teaches that sensing a muscle tone in the pectoral region is “equally as effective” as another way of detecting REM sleep. The undersigned has reviewed Forbes, particularly the cited passage at column 3, lines 13-16, and can find no disclosure therein of either (1) sensing a muscle tone in a pectoral region, or (2) characterizing or comparing the effectiveness of detecting REM sleep by sensing muscle tone in the pectoral region with the effectiveness of detecting REM sleep in another way. Since the rejection is premised on an erroneous assessment of the scope and content of Forbes, the rejection of claims 86 and 104, and of their respective dependent claims, cannot be sustained.

The claim rejections are thus premised on erroneous grounds and on erroneous characterizations of at least Cho and Forbes, and cannot be sustained. This Appellant’s Statement, viewed together with the prosecution history, sets forth clear grounds for a finding that the rejections of record are without merit.

Respectfully submitted,

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